

**Remarks**

Claims 176, 177 and 178 have been amended to recite that single or multiple readouts are determined. Support for these amendments can be found in the specification on page 5, lines 31-33, page 6, lines 4-17, page 20, lines 30-32 and page 22, lines 28-30.

Claims 28, 29, 31, 35, 45, 95, 117-139 and 176-178 are pending for examination with claims 28, 35, 45 and 95 being independent claims.

Claims 35, 45, 95 and 121-139 have been allowed.

No new matter has been added.

**Allowable Subject Matter**

The Examiner has found the Applicant's previous arguments filed July 12, 2004, with respect to claims 28, 29, 31, 45, 95 and 117-139 under 35 U.S.C. 102(b), persuasive and has withdrawn this rejection.

Claims 35, 45, 95 and 121-139 have been allowed. The Examiner states that "the prior art does not teach or suggest that a ratio of the amount of total liver FAEE to the amount of total adipose FAEE of at least 2 is indicative of ethanol intake" and that it "does not teach or suggest ethyl arachidonate in at least 200 pmol/gram in the tissue, singularly, to indicate ethanol intake".

**Rejections under 35 U.S.C. §112, first paragraph**

Claims 176-178 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Examiner requests further clarification of the support for the claimed readouts.

Applicant has amended claims 176-178 to recite that single or multiple readouts are determined. Support for these amendments can be found in the specification on page 5, lines 31-33, page 6, lines 4-17, page 20, lines 30-32 and page 22, lines 28-30. Specifically, page 5, lines 31-33 state that "the invention provides a method for determining ethanol intake by a subject using a single or a combination of parameters". Accordingly, there is sufficient written description to support claims 176-178 as previously pending and as currently amended.

Withdrawal of the rejection under 35 U.S.C. §112, first paragraph, is respectfully requested.

**Rejections under 35 U.S.C. §103(a)**

Claims 28, 29, 31 and 117-120 are rejected under 35 U.S.C. §103(a) as being unpatentable over Laposata, 1998, Prog. Lipid. Res., 37(5):307-316. According to the Examiner, the reference “differs from the instantly claimed invention in that its determination of FAEE is not exclusive to liver and adipose tissue samples”. However, the Examiner states that the claims “would read on a method of determining the total FAEE derived from many sources” in view of the comprising language. The Examiner further states that although Laposata “does not expressly disclose the amount of FAEE that is present in order to make the determination of ethanol intake, ... it would have been obvious to one having ordinary skill in the art to modify the Laposata reference by selecting any number within the elevated range with the expectation that samples equaling or exceeding that amount would be reliable indicators of ethanol intake”.

Applicants respectfully traverse because the Examiner has not met her burden of establishing a *prima facie* case of obviousness. The Examiner has failed to establish motivation to modify or change the teachings of the Laposata reference (and thus a reasonable expectation of success in making such a modification), and, even if such motivation existed, that it would yield each and every element of the rejected claims.

The rejected claims relate to determining the amount of total FAEE in a liver sample and an adipose tissue sample and adding the two amounts to produce a combined total FAEE amount which, if greater than 2000 pmol/gram, is indicative of ethanol intake.

There is no motivation or suggestion to modify the teachings of the reference to arrive at the rejected claims. The Laposata reference summarizes a number of earlier studies that analyzed FAEE content in individual tissues including adipose tissue and liver. The reference does not recommend or suggest improvement of any of these specific measurements. Rather, the reference adds to these studies by determining FAEE content in blood and concludes that “FAEE in the blood can serve as an excellent short-term confirmatory test for ethanol intake as well as a long-term marker of ethanol ingestion”. Although the Examiner states that “the total FAEE in Laposata would include an addition of the FAEE from all ... sources”, she provides no basis for this statement. None of the sections highlighted by the Examiner support her statement, and neither does a more complete reading of the reference.

In addition, the Examiner appears to suggest that the reference and the comprising language support addition of FAEE from pancreas, liver, heart, brain and adipose tissues. Thus, even if there existed a motivation to modify the reference teachings (and Applicants maintain there is not), according the Examiner, the modification would be addition of FAEE from all of these sources, and not from liver and adipose specifically, as recited in the rejected claims.

There is nothing in the reference itself or in the knowledge in the art at the time of the invention to suggest *combining liver and adipose FAEE content* and using this combined total as a marker of ethanol intake. In the same light, there can be no reasonable expectation of success for such a modification at least because there is no motivation or suggestion to modify in the first place.

Notwithstanding, even if such modification existed, it would still not yield each and every element of the rejected claims. There is nothing in the Laposata reference or in the knowledge in the art at the time of the invention that identifies or prefers the selection and combination of liver and adipose FAEE contents in order to arrive at a sum total that can be used as an indicator of ethanol intake. There is similarly no indication in Laposata or in the art of the particular threshold level that clearly discriminates between ethanol intake and non-ethanol intake, as recited in the rejected claims.

Contrary to the Examiner's assertion, the "comprising" language of the claims does not render obvious the claims in view of the Laposata reference because the claims recite *additional* steps not found in the reference. The Examiner's argument can only apply if all elements of the rejected claims are already taught by the reference. As stated above, this is not the case. There is no basis for the Examiner's view that the reference teaches addition of FAEE specifically from liver and adipose tissue, as recited in the rejected claims. That teaching can only be found in the instant disclosure. The Examiner is engaging in hindsight in concluding that the reference teaches such a combination, and this is impermissible.

Withdrawal of this rejection under 35 U.S.C. §103(a) is respectfully requested.

**CONCLUSION**

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,  
*Michael Laposata, Applicant*



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